THE CLAIMS

What is claimed is:

1. A method of treating or preventing sexual dysfunction which comprises administering to a patient in need of such treatment or prevention therapeutically or prophylactically effective amounts of a sibutramine metabolite, or a pharmaceutically acceptable salt, solvate, hydrate, clathrate, or prodrug thereof, and a phosphodiesterase inhibitor.

2. The method of claim 1 wherein the sibutramine metabolite is optically pure.

3. The method of claim 2 wherein the sibutramine metabolite is (R)-desmethylsibutramine, (S)-desmethylsibutramine, (R)-didesmethylsibutramine, or (S)-didesmethylsibutramine.

4. The method of claim 1 wherein the phosphodiesterase inhibitor is a PDE5 or PDE6 inhibitor.

5. The method of claim 4 wherein the phosphodiesterase inhibitor is sildenophil, desmethylsildenophil, vinopocetine, milrinone, amrinone, pimobendan, cilostamide, enoximone, peroximone, vesnarinone, rolipram, R020-1724, zaprinast, dipyridamole, or a pharmaceutically acceptable salt, solvate, hydrate, clathrate, prodrug, optically and pharmacologically active stereoisomer, or a pharmacologically active metabolite thereof.

6. The method of claim 1 wherein the amount of sibutramine metabolite administered is from about 0.1 mg to about 60 mg/day.

7. The method of claim 6 wherein the amount of sibutramine metabolite administered is from about 2 mg to about 30 mg/day.

8. The method of claim 7 wherein the amount of sibutramine metabolite administered is from about 5 mg to about 15 mg/day.

9. The method of claim 1 wherein the sibutramine metabolite and/or the phosphodiesterase inhibitor is administered transdermally or mucosally.

10. The method of claim 1 wherein the patient is male.

11. The method of claim 10 wherein the sexual dysfunction is erectile dysfunction.

12. The method of claim 1 wherein the patient is female.

13. A method of treating or preventing a cerebral function disorder which comprises administering to a patient in need of such treatment or prevention therapeutically or prophylactically effective amounts of a sibutramine metabolite, or a pharmaceutically acceptable salt, solvate, hydrate, clathrate, or prodrug thereof, and a phosphodiesterase inhibitor.

14. The method of claim 13 wherein the cerebral function disorder is senile dementia, Alzheimer's type dementia, memory loss, amnesia/amnestic syndrome, disturbance of consciousness, coma, lowering of attention, speech disorders, Parkinson's disease, Lennox syndrome, autism, epilepsy, hyperkinetic syndrome, or schizophrenia.

15. The method of claim 13 wherein the sibutramine metabolite is optically pure.

16. The method of claim 15 wherein the sibutramine metabolite is (R)-desmethylsibutramine, (S)-desmethylsibutramine, (R)-didesmethylsibutramine, or (S)-didesmethylsibutramine.

17. The method of claim 13 wherein the phosphodiesterase inhibitor is a PDE5 or PDE6 inhibitor.

18. The method of claim 17 wherein the phosphodiesterase inhibitor is sildenophil, desmethylsildenophil, vinopocetine, milrinone, amrinone, pimobendan, cilostamide, enoximone, peroximone, vesnarinone, rolipram, R020-1724, zaprinast,

dipyridamole, or a pharmaceutically acceptable salt, solvate, hydrate, clathrate, prodrug, optically and pharmacologically active stereoisomer, or a pharmacologically active metabolite thereof.

19. The method of claim 13 wherein the amount of sibutramine metabolite administered is from about 0.1 mg to about 60 mg/day.

20. The method of claim 19 wherein the amount of sibutramine metabolite administered is from about 2 mg to about 30 mg/day.

21. The method of claim 20 wherein the amount of sibutramine metabolite administered is from about 5 mg to about 15 mg/day.

22. A method of treating or preventing restless leg syndrome which comprises administering to a patient in need of such treatment or prevention a therapeutically or prophylactically effective amount of a racemic or optically pure sibutramine metabolite, or a pharmaceutically acceptable salt, solvate, clathrate, or prodrug thereof.

23. The method of claim 22 wherein the sibutramine metabolite is optically pure.

24. The method of claim 23 wherein the sibutramine metabolite is (R)-desmethylsibutramine, (S)-desmethylsibutramine, (R)-didesmethylsibutramine, or (S)-didesmethylsibutramine.

25. The method of claim 22 which further comprises the administration of pergolide, carbidopa, levodopa, oxycodone, carbamazepine, or gabapentin, or a pharmaceutically acceptable salt, solvate, hydrate, clathrate, prodrug, optically and pharmacologically active stereoisomer, or pharmacologically active metabolite thereof.

26. A pharmaceutical composition comprising a sibutramine metabolite, or a pharmaceutically acceptable salt, solvate, hydrate, clathrate, or prodrug thereof, and a phosphodiesterase inhibitor.

27. The pharmaceutical composition of claim 26 wherein the sibutramine metabolite is optically pure.

28. The pharmaceutical composition of claim 27 wherein the sibutramine metabolite is (R)-desmethylsibutramine, (S)-desmethylsibutramine, (R)-didesmethylsibutramine, or (S)-didesmethylsibutramine.

29. The pharmaceutical composition of claim 28 wherein the phosphodiesterase inhibitor is sildenophil, desmethylsildenophil, vinopocetine, milrinone, amrinone, pimobendan, cilostamide, enoximone, peroximone, vesnarinone, rolipram, R020-1724, zaprinast, dipyridamole, or a pharmaceutically acceptable salt, solvate, hydrate, clathrate, prodrug, optically and pharmacologically active stereoisomer, or a pharmacologically active metabolite thereof.

30. The pharmaceutical composition of claim 26 wherein the sibutramine metabolite is in an amount of from about 0.1 mg to about 60 mg.

31. The pharmaceutical composition of claim 30 wherein the sibutramine metabolite is in an amount of from about 2 mg to about 30 mg.

32. The pharmaceutical composition of claim 31 wherein the sibutramine metabolite is in an amount of from about 5 mg to about 15 mg.

33. The pharmaceutical composition of claim 26 wherein the phosphodiesterase inhibitor is in an amount of from about 0.5 mg to about 500 mg.

34. The pharmaceutical composition of claim 33 wherein the phosphodiesterase inhibitor is in an amount of from about 1 mg to about 350 mg.

35. The pharmaceutical composition of claim 34 wherein the phosphodiesterase inhibitor is in an amount of from about 2 mg to about 250 mg.

36. The pharmaceutical composition of claim 26 wherein the pharmaceutical composition is adapted for oral, mucosal, rectal, parenteral, transdermal, or subcutaneous administration.

37. The pharmaceutical composition of claim 36 wherein the pharmaceutical composition is adapted for oral, mucosal, or transdermal administration.

38. A lactose-free pharmaceutical composition which comprises a sibutramine metabolite, or a pharmaceutically acceptable salt, solvate, or clathrate thereof, a phosphodiesterase inhibitor, and a pharmaceutically acceptable excipient.

39. The pharmaceutical composition of claim 38 wherein the excipient is croscarmellose sodium, microcrystalline cellulose, pre-gelatinized starch, or magnesium stearate.

40. The pharmaceutical composition of claim 39 wherein said pharmaceutical composition is substantially free of mono- or di-saccharides.